

EXHIBIT A

In Re:

Digitek

Richard Dowling

December 16, 2009

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1 double thickness. Maybe I shouldn't -- strike
2 my question. Let me try it again.

3 Double thickness pills, do you
4 remember that incident?

5 MR. ANDERTON: Objection.

6 You may answer.

7 THE WITNESS: Yes.

8 BY MR. THOMPSON:

9 Q Do you remember on November 30,
10 2007, there were a series of double thickness
11 digoxin or Digitek pills that were stamped?
12 Do you recall that incident?

13 MR. ANDERTON: Objection.

14 You may answer.

15 THE WITNESS: I recall double
16 thick tablets. I don't recall the
17 specific date you mentioned.

18 BY MR. THOMPSON:

19 Q And do you recall that the lot
20 number from which those double-stamped --
21 double thickness pills were stamped, do you
22 recall that lot number was recalled from the
23 market?

24 A I don't know. I don't know that lot

1 number.

2 Q Now, my question -- that leads up to
3 this question: These three
4 out-of-specification results have nothing to
5 do with double thickness digoxin pills,
6 tablets, does it?

7 A No.

8 Q These three lots of Digitek have to
9 do with an improper or incomplete blending of
10 ingredients; isn't that right?

11 MR. ANDERTON: Objection.

12 You may answer.

13 THE WITNESS: No, not
14 necessarily.

15 BY MR. THOMPSON:

16 Q What were the three
17 out-of-specifications results that are
18 referred to in this observation for?

19 A Blend uniformity.

20 Q Okay. And that would be a sample
21 was taken from a part of the blender and that
22 sample showed that the blending was not
23 uniform; is that right?

24 MR. ANDERTON: Objection; asked

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1 reading that.

2 BY MR. THOMPSON:

3 Q Actually, I don't want you to recall
4 reading it. Do you recall the FDA being
5 brought in to I guess stamp or to approve the
6 new production?

7 A Yes, they were called in to approve
8 that facility.

9 Q And instead, after that inspection,
10 you got a series of observations and a series
11 of recalls and then a shuttering of the plant;
12 is that right?

13 MR. ANDERTON: Objection.

14 You may answer.

15 THE WITNESS: We did get
16 observations, yes, during that
17 inspection, yes.

18 (Plaintiff's Exhibit No. 97 was
19 marked for identification.)

20 BY MR. THOMPSON:

21 Q I'll hand you Plaintiff's Exhibit
22 97. Okay. Now, Mr. Dowling, this is an
23 e-mail from you to Bharat Patel and Apurva
24 Patel. It says "new punches Digoxin," dated

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1 December 18, 2007; is that right?

2 A Yes.

3 Q It says: "As part of the corrective
4 action for investigation number 07-093 for
5 Digoxin double tablets, I am going to state
6 that we will buy a complete set of lowers and
7 dies for both strengths of Digoxin that will
8 be dedicated and not used for any other
9 products. It is possible the tablet stuck to
10 the punch and was double compressed.

11 "In addition, we should immediately
12 do the same for the three strengths of --
13 blank or redacted -- right away.

14 "In the long run, the lower punches
15 and dies will last longer if they are
16 dedicated and not used for multiple products,
17 and we won't have to delay set-ups because the
18 lowers or dies needed are in use and not
19 available."

20 Okay? You wrote that; right?

21 A Yes.

22 Q Now, as of December 18, 2007, you
23 did not have a set of lowers and dies that
24 were dedicated solely to use to produce

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1 digoxin; isn't that right?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: We had lower
5 punches and dies as indicated in the
6 production batch record available to use
7 for digoxin.

8 BY MR. THOMPSON:

9 Q Right. But the punches and dies
10 were not reserved solely to use for digoxin,
11 were they?

12 A The lowers and dies were used
13 interchangeably.

14 Q Okay. So when you say
15 "interchangeably," you're saying that the
16 lowers and the dies were used for digoxin and
17 for other products as well; isn't that right?

18 A Yes, they could be used for other
19 products.

20 Q And what other products were they
21 used for?

22 A That I don't recall. They would be
23 products with the same die characteristic or
24 size or the same punch or tablet

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1 configuration.

2 (Plaintiff's Exhibit No. 98 was
3 marked for identification.)

4 BY MR. THOMPSON:

5 Q Keep that one right beside it and
6 let me hand you Plaintiff's Exhibit 98. Did
7 you have a chance to look this over before you
8 came to the deposition today?

9 A Yes, I did.

10 Q Okay. Now, this is an affidavit.
11 And you're aware that an affidavit is a
12 document that's under oath; correct?

13 A Yes.

14 Q And so it's sworn testimony. Now,
15 if I turn to Paragraph 14, read that for me.

16 MR. ANDERTON: I'm sorry. What
17 number?

18 MR. THOMPSON: No. 14.

19 THE WITNESS: "Digitek is
20 produced using what effectively is a
21 custom, Digitek-only tablet press. The
22 base model and make of the tablet press
23 used to manufacture all of the recalled
24 Digitek is a 45 station Stokes BB2 tablet